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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AIDS HEALTHCARE FOUNDATION, INC., Plaintiff, **v.** **GILEAD SCIENCES, INC.; JAPAN TOBACCO, INC.; JAPAN TOBACCO INTERNATIONAL U.S.A., INC.; AKROS PHARMA, INC.; JANSSEN SCIENCES IRELAND UC; AND JOHNSON & JOHNSON, INC.** Defendants	**Case No. : 3:16-cv-00443-WHA** **COMPLAINT FOR** **1. DECLARATORY JUDGMENT OF PATENT INVALIDITY;** **2. VIOLATIONS OF THE SHERMAN ACT, 15 U.S.C. §§ 1 & 2;** **3. CALIFORNIA CARTWRIGHT ACT;** **4. CALIFORNIA BUSINESS & PROFESSIONS CODE § 17200; AND** **5. NEVADA UNFAIR TRADE PRACTICES LAW** **JURY TRIAL DEMANDED**

AIDS Healthcare Foundation ("AHF"), the largest non-profit provider of specialized HIV/AIDS medical care in the United States brings this action to stop Gilead Sciences, Inc. ("Gilead") from blocking affordable access to a lifesaving HIV drug - Tenofovir Alafenamide ("TAF").

I. INTRODUCTION

1. In a relentless effort to maximize its profits, Gilead manipulated the patent system and engaged in anticompetitive practices to prevent economical access to TAF – an antiviral agent used in the treatment of HIV. TAF is not a new compound. TAF is a prodrug[1] of the compound Tenofovir, which was first synthesized over thirty years ago in the Czech Republic. Nor was TAF the first prodrug of Tenofovir. Several years before Gilead obtained a patent on TAF, Gilead had patented a similar prodrug called Tenofovir Disoproxil ("TDF"). Despite similarities between TAF and TDF and the weakness of the patents covering TAF, Gilead illegally seeks to extend the period of patent exclusivity for drugs incorporating Tenofovir by decades.

2. Gilead's attempt to extend the period of patent exclusivity for drugs incorporating Tenofovir arises from Gilead manipulating the patent system, entering into a licensing agreement with Japan Tobacco, and expanding its licensing agreement with Johnson & Johnson subsidiary Janssen Sciences to block entry by potential competitors and prevent competition.

3. Gilead readily admits its monopoly power over TAF: "Gilead received five years of regulatory exclusivity, running to at least November 2020, during which no generic form of TAF can be approved by the FDA ('NCE exclusivity')."[2] Gilead further states that its NCE exclusivity "prevents anyone from filing for FDA approval of any version of TAF until late 2019 . . . ."[3]

4. To effectively treat and manage HIV, physicians utilize multiple drugs in what is

[1] Prodrugs are medicines that are converted into their active form once they are processed inside the body. In the case of TAF, it is taken orally and after absorption it passes into the blood.

[2] *AIDS Healthcare Foundation, Inc. v. Gilead Sciences, Inc., et al.*, Case No. 3:16-cv-004433-WHA, Dkt. No. 29, at 1 (N.D. Cal. March 21, 2016).

[3] *Id.* at 9.

known as "highly active antiretroviral therapy" ("HAART.") Tenofovir-containing prodrugs (TDF and now TAF) are important components of a HAART regimen, but they are merely one of many necessary components. Critical to the success of HAART is the flexibility to substitute various drugs (and dosages of those drugs) comprising a given patient's regimen. Depending upon the specific conditions and symptoms exhibited by a given patient, physicians rely on the following complementary drugs in combination with Tenofovir-containing prodrugs: dolutegravir, lamivudine, emtricitabine, raltegravir, ritonavir, darunavir, efavirenz, elvitegravir, cobicistat, rilpivirine, etc. Physicians prescribe these drugs in various combinations, and at various dosages in an effort to optimize HAART.

5. Gilead uses its ill-gotten monopoly in the TAF market to illegally tie the sale of other drugs Gilead developed or drugs that it has licensed from Japan Tobacco and Janseen Sciences. The tying of other products to the sale of TAF allows Gilead to monopolize the market for HAART products and earn profits that it would not otherwise receive. Further, Gilead's illegal tying activities prevents healthcare providers, doctors, and patients from being able to control healthcare decisions.

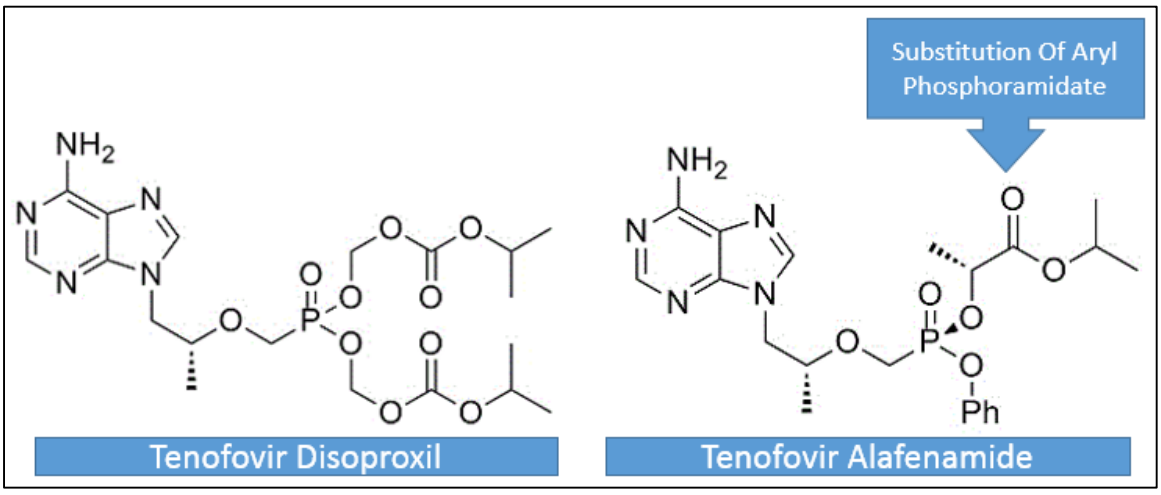
6. Gilead's actions have directly harmed AHF, which in 2015 alone purchased millions of dollars of HAART-related drugs from Gilead.

7. In the first three quarters of 2015, Gilead sold over fifteen billion dollars of HIV antiviral drugs in the United States. Roughly 80% of these drugs incorporate a prodrug of Tenofovir called Tenofovir Disoproxil ("TDF"). TDF and TAF are both prodrugs and very closely related. The patents on TDF expire in 2017 and 2018. The impending expiration of the TDF patents presented a financial challenge to Gilead, as Gilead was heavily reliant on the patent exclusivity period of the TDF patents to prevent entry by generic pharmaceutical makers. The expiration of the TDF patents would leave Gilead with no patent exclusivity relating to Tenofovir, as the compound patent had expired and the prodrug formulation (TDF) was about to expire. Instead of allowing the patents to expire and generics to enter the market, thus helping to lower the prices of necessary medications for HIV patients, Gilead developed a complex,

anticompetitive scheme to extend its exclusivity on drugs incorporating Tenofovir.

8. ***First***, Gilead did not conduct clinical trials in humans using TAF until 2011 despite presenting test tube and animal data on the use of TAF ten years prior. By waiting to take TAF to clinical trial just years prior to TDF's patent expiration (December 2017), Gilead was able to extend its exclusivity period for TAF by years. Had Gilead not delayed in bringing TAF to clinical trials, Gilead's patent exclusivity on TAF would be significantly shorter. The delay in conducting clinical trials deprived those suffering from HIV of TAF for more than a decade. These people suffering with HIV were forced to take TDF, which because of TDF's lower absorption rates had higher bone and kidney toxicities.[4] It is possible that HIV patients suffered from 10 years of additional accumulated kidney and bone toxicity using TDF while TAF stayed on the shelf.

9. ***Second***, Gilead sought patent protection on another prodrug formulation of Tenofovir that would have been obvious at the time. Given the existing prior knowledge for formulating antiviral compounds as prodrugs to allow intracellular absorption, substituting the disoproxil ester of Tenofovir with an aryl phosphoramidate ester was an obvious substitution. Similarly, the use of fumarate salt for formulation purposes was obvious in light of Gilead's



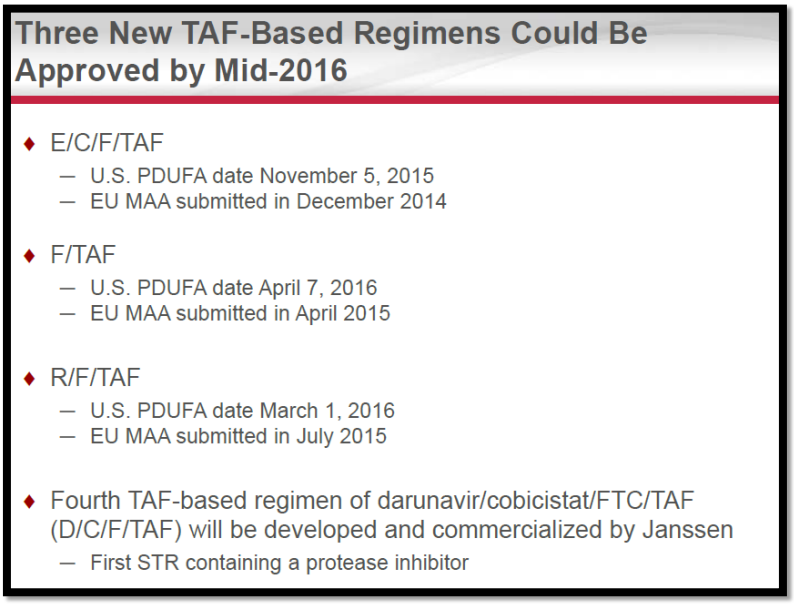
[4] Gilead's Chairman and CEO John Martin has trumpeted the superior safety of TAF over TDF as a reason for customers to switch. "[TAF] has a superior safety profile compared to TDF. This is important because most newly diagnosed patients will now be treated for decades, and at the same time, many HIV-infected individuals who are in treatment, particularly in the U.S. and Europe, are advancing in age." Q2 2015 Gilead Earnings Call (Jul 29, 2015).

already patented TDF prodrug.

10. The patents Gilead has sought and been granted allow Gilead to exclude generic competition if those patents remain unchallenged. The TAF patents also have extended by at least seven years the patent exclusivity period that Gilead has for drugs incorporating Tenofovir to combat HIV. Patent expiration dates are critical to preserving the price of a drug. Internal documents from Gilead have shown that revenues on a drug going off patent decay 20% the first year and 50% per year for the following three years.[5] AHF seeks a declaratory judgment that the patents covering TAF are invalid.

11. Because of the weakness of Gilead's patents covering TAF, Gilead has engaged in anticompetitive business practices aimed at keeping competing TAF drugs off the market for years. Gilead has and continues to make TDF available as a standalone product under the brand drug Viread. Viread's only active ingredient is TDF, and Gilead has repeatedly stated that TAF is an alternative to TDF whose significant difference is that it is absorbed more efficiently and thus avoids bone and kidney toxicity. The failure to make TAF available as a standalone drug highlights Gilead's motive of avoiding competition at all costs.

[5] Gilead Project Harry – Model Discussion, U.S. Senate Report at GS-0005534 (August 16, 2011).



Gilead Third Quarter Earnings Slides, GILEAD FINANCIAL PRESENTATION at 12 (October 27, 2015) (showing that Gilead intends to offer TAF only in combination with other drugs. This allows Gilead to hide behind comparatively stronger patents of the other drugs included in the combination products and avoid potential challenges to the weak TAF patents.).

12. ***Third***, Gilead has entered into licensing agreements with Japan Tobacco and Janssen Sciences to develop and sell compound drugs that enjoy the patent protections of not only the TAF patents, but also the patents that cover the other pharmaceutical compounds in these combination drugs. Further, Gilead has failed to make TAF available in a standalone drug where its weak patents would more likely be challenged. Under the Hatch-Waxman regulatory regime, a generic manufacturer entering the market would have to invalidate the TAF patents as well as the patents that cover the three other compounds in the combination drug. Gilead has tactically chosen to not offer a standalone TAF drug so that any generic maker entering the market would be forced to either challenge several patents covering two or more separate pharmaceutical compounds, or go through the years-long and incredibly expensive process of conducting clinical trials.

13. ***Fourth***, Gilead is using its licensing agreements with Japan Tobacco and Janssen Sciences to utilize its monopoly power in TAF to force patients to purchase complementary drugs used in the treatment of HIV. Patients (and prescribing physicians) that need access to TAF have no choice but to take it in combination with drugs selected by Gilead, and at dosages selected by

Gilead.

14. Gilead's November 2015 release of the brand drug Genvoya (which incorporates TAF) is indicative of the anti-competitive strategy employed by Gilead to protect TAF from a patentability challenge directly. Genvoya is a fixed-dose combination tablet containing elvitegravir, cobicistat, emtricitabine, and TAF. Because Genvoya contains three compounds in addition to TAF, Gilead is able to list twelve patents as covering Genvoya in the FDA's Orange Book. A generic wishing to enter the market (pursuant to Hatch-Waxman regulations) has to prove non-infringement or invalidity of twelve patents versus the three weak patents that are specific to TAF. Gilead, by entering into exclusive license agreements with Japan Tobacco and Janssen and illegally tying the availability of TAF to compounds such as elvitegravir and rilpivirine, has engaged in a conspiracy in restraint of trade in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, California state law, and Nevada state law.

15. Gilead followed the release of Genvoya with the release of Odefsey and Descovy– all combination drugs released by Gilead containing TAF. Odefsey was released in March 2016 and contains emtricitabine and rilpivirine in addition to TAF. By purchasing the rights to emtricitabine from Emory University[6] and entering into a licensing agreement with Janssen Sciences, Gilead has engaged in illegally tying the sale of TAF to the sale of emtricitabine and rilpivirine. Gilead's actions are a conspiracy in restraint of trade in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, California state law, and Nevada state law.

16. Many HIV patients have difficulty tolerating TDF due to increased kidney and bone toxicity levels caused by TDF. TAF alleviates some of these issues. However, Gilead has refused to produce a standalone TAF drug. In so doing, Gilead is illegally tying the sale of TAF to other drugs:

- Genvoya: elvitegravir, cobicistat, and emtricitabine

[6] In 2005, Gilead purchased the royalty rights to emtricitabine from Emory University for 525 million dollars. Any additional sales that Gilead is able to generate through tying emtricitabine to the sale of TAF accrue almost entirely to Gilead. There is a 35% royalty that goes to Royalty Pharma contingent on several preconditions. *See* GILEAD SCIENCES EMORY UNIVERSITY ROYALTY SALE AGREEMENT (July 18, 2005).

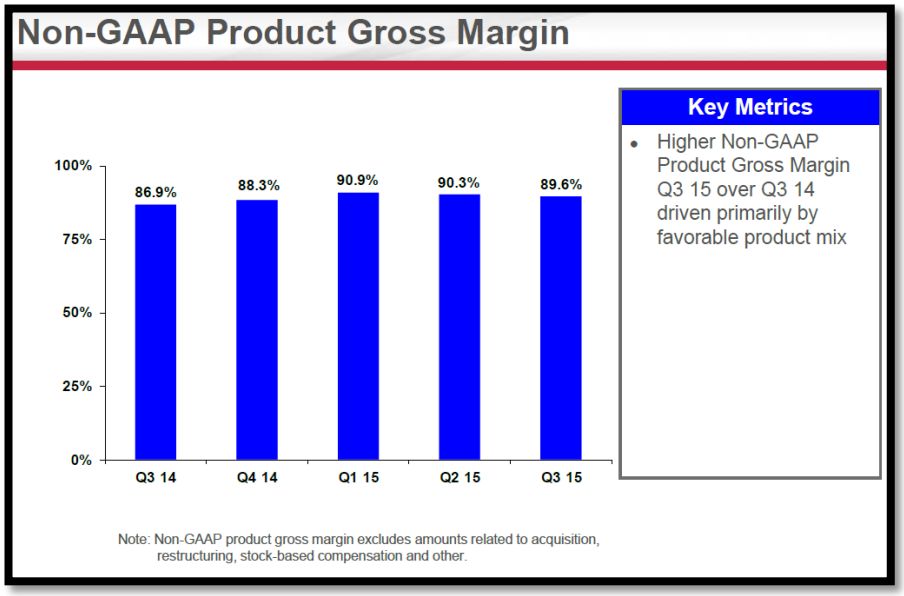
- Odefsey: emtricitabine and rilpivirine
- Descovy: emtricitabine

17. Gilead's release of varying different formulations of TAF-containing products underscores TAF's ability to be prescribed with a wide variety of complementary drugs as part of a HAART therapy. However, Gilead's refusal to release a standalone version of TAF deprives AHF physicians of the ability to tailor HAART regiments for patients that include TAF. Gilead's business practices also force AHF, as a requirement of obtaining TAF, to purchase quantities of elvitegravir, cobicistat, emtricitabine, and rilpivirine far greater than it desires.

18. Gilead's illegal tying activities economically harms AHF. AHF is forced to purchase these tied drugs to obtain TAF. In addition, Gilead's business practices rob AHF physicians of the ability to utilize TAF as part of a HAART regimen other than the exact combination of drugs and dosages included in Genvoya, Odefsey, or Descovy.

19. Gilead's tactics have allowed Gilead to reap outsized profits, and if allowed to continue, will harm the public and AHF. In 2015, Gilead was able to earn 90% Non-GAAP Product Gross Margins. Gilead's tactics led the New York Times to comment, "Gilead now is faced with figuring out ***what to do with all the cash it is generating***."[7]

[7] Andrew Pollack, *Sales of Solvadi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion,* NY TIMES (February 4, 2015) (emphasis added).



Gilead Third Quarter Earnings Slides, GILEAD FINANCIAL PRESENTATION at 39 (October 27, 2015).

20. By maintaining exorbitant pricing for antiviral drugs, Gilead can rely on gamesmanship to avoid competition rather than expending money on research and development of new drugs. Gilead, in its 2015 Guidance stated that it anticipated spending between 2.8 and 3 billion dollars on research and development, while earning a profit of roughly 23 billion dollars.[8]

21. The high prices of antiviral drugs impact the availability of these lifesaving drugs for the public. High prices of drugs such as Gilead's Genvoya ($31,362 per year), Odefsey, and Descovy, limit patient access either through exorbitant co-pays, limitations in existing insurance, and rationing of these high priced pills. The high price of Gilead's Hepatitis C treatment has led many state Medicare programs to limit the number of infected people who will actually receive treatment. High prices have forced Medicare patients to wait indefinitely for access to Gilead's drug while continuing to suffer the effects of Hepatitis C, including liver failure, liver cancer, and blood disorders. Gilead's pricing of its Hepatitis C drug led to a United States Senate Investigation in 2015 and the release of a report that found, "It was always Gilead's plan to maximize revenue, and affordability and accessibility was an afterthought."[9]

[8] Gilead Guidance for 2015, Q3 2015 Earnings Slides at 2 (October 27, 2015).

[9] Bill Berkrot, *Gilead Put Profit Ahead of Hepatitus C Patients: U.S. Senate Report*, REUTERS

22. By preventing competition through manipulation of the patent system and the Hatch-Waxman provisions that encourage generic competition, Gilead is able to impose costs on AHF and the public by maintaining artificially high pricing for drugs containing TAF. The United States Senate Report on Gilead's pricing of another antiviral drug (Sovaldi) found, "Without successful competition, the costs to the public and private payers could have caused much more significant disruptions and access restrictions for years."[10]

23. AHF has been directly impacted by Gilead's scheme to maintain inflated pricing for drugs containing TAF. AHF has had to pay inflated pricing for Genvoya, Odefsey, and Descovy and anticipates that, because of a lack of generic competition and Gilead's blocking the market for generic entry through its invalid patents and anticompetitive practices, AHF will be forced to continue to pay exorbitant and unwarranted costs for years to come on Genvoya, Odefsey, Descovy, and any other combination drugs containing TAF released by Gilead. AHF respectfully requests that the Court enter a declaration that United States Patent Nos. 7,390,791; 7,800,788; 8,754,065; 8,148,374; and 8,633,219 are invalid under 35 U.S.C. §§ 101 *et seq*. Further, AHF requests that the Court find the acts and conduct of Defendants unlawful violations of the Sherman Act, California state law, and Nevada state law.

II. THE PARTIES

A) AIDS Healthcare Foundation

24. Established in 1987, AHF is the largest non-profit provider of specialized HIV/AIDS medical care in the United States. AHF provides large-scale HIV counseling and testing services, early intervention services, HIV medical care, research on HIV care and treatment, medical case management, pharmacy services, referrals, and innovative client retention protocols.

25. AHF is a non-profit organization in Los Angeles, California, having a principal

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NEWS (December 1, 2015) (quoting Senator Ron Wyden); *Gilead Focused On Profit, Not Patients, Senate Report Concludes*, SFGate.com (December 1, 2015) ("The evidence shows the company pursued a calculated scheme for pricing and marketing its hepatitis C drug based on one primary goal — maximizing revenue — regardless of the human consequences").

[10] The Price of Sovaldi and Its Impact on the U.S. Health Care System at 120 (December 2015).

place of business at 6255 W. Sunset Boulevard, 21st floor, Los Angeles, California, 90028. AHF has 3,350 employees worldwide. AHF operates 46 Healthcare Centers in the United States spread through 14 states and the District of Columbia, including California and Nevada. Worldwide, AHF has 575,000 patients and clients.

26. AHF also operates managed care programs for people living with HIV and/or AIDS. There are currently 4,700 individuals enrolled in its care plans.

27. AHF placed its first order for Genvoya on November 9, 2015. AHF primarily orders Genvoya from Cardinal Health. Cardinal is one of 25 Gilead Authorized Distributors of Record.[11] Gilead has shipped Genvoya and other HIV medication directly to a facility operated by AHF.

28. AHF has placed orders for Odefsy and Descovy for its pharmacies located in California and Nevada.

29. In 2015, AHF purchased millions of dollars of antiviral pharmaceutical drugs from Gilead.

30. On January 21, 2016, AHF sent a letter (attached as Exhibit A) to Dawn Dyna, Sr. Manager of Governmental Contracts at Gilead, "formally request[ing] that Gilead Sciences, Inc. [] permit our organization to purchase tenofovir alafenamide as a stand-alone product."

31. AHF has requested to place orders with pharmaceutical manufacturers to make a standalone TAF product. Because Gilead claims its patents cover TAF, these drug makers have refused to provide AHF with a standalone version of TAF. Gilead's prevention of the development of standalone TAF negatively affects AHF's patients and clients by preventing them from gaining access to TAF. Competitor pharmaceutical companies' entry into the market and/or provision of drugs containing TAF would put AHF at risk of liability as an indirect infringer of Gilead's patents covering TAF.

32. The long history of disputes between Gilead and AHF relating to antiviral drugs

[11] Authorized Distributors of Record, Gilead Website (last visited January 23, 2016), available at: http://www.gilead.com/medicines/authorized-distributors

has given AHF a reasonable apprehension that it would face a patent infringement suit from Gilead were it to sell, import, develop, distribute, and/or test an unlicensed drug containing TAF. The parties have a history of disputes regarding the patents to HIV compounds. These disputes are likely to continue for the foreseeable future. AHF and Gilead thus have adverse legal interests over a dispute of sufficient reality that is capable of conclusive resolution through a declaratory judgment. The longstanding disputes between AHF and Gilead that provide AHF with a reasonable apprehension of suit include: (1) In March 2008, AHF petitioned drug manufacturers including Gilead to freeze the price of their HIV drugs in the U.S. (2) AHF's January 2016 complaint against Gilead for Truvada PrEP ads promoting off-label use of Truvada. AHF filed a complaint with the FDA asking that Gilead be held accountable for promoting off-label use of Truvada. (3) A January 2014 dispute between AHF's President, Michael Weinstein, and Gilead regarding a shareholder proposal submitted to Gilead by Mr. Weinstein requesting that compensation for the chief executive officer should include non-financial measures based on patient access to Gilead's medicines. Mr. Weinstein proposed this resolution after Gilead's chief executive was paid 90 million dollars in 2013.[12] Gilead opposed the resolution and claimed it was "another tactic calculated to pressure the Company [Gilead].").[13] (4) AHF's Freedom of Information Act lawsuit to release Gilead documents and testing information relating to Truvada.

33. AHF's has been taking steps to distribute and purchase generic versions of TAF either as a standalone pill to be used in HAART or as part of a combination drug formulation. Specifically, AHF's Pharmacy Supply Chain Manager, David Fitzpatick has contacted Brendan O'Grady, Chief Executive Officer of Teva North America; Rajeev TL, General Manager of Business Development and Sales Management at Aurobindo Pharma USA, Inc.; Paul McGarty, President of Lupin Pharmaceuticals, Inc. USA; and Kurt Nielsen, Vice Present, Development,

[12] Martin Sasnoff, The Rapacious Enrichment of Gilead's CEO, Forbes Markets (April 1, 2014) ("Gilead's CEO John Martin took home more than $90 million making him one of the 10 highest paid CEO's in the country. His 5-year compensation exceeded $250 million.").

[13] Brett Pletcher, *Correspondence to the Securities and Exchange Commission* (February 4, 2014), available at: http://www.sec.gov/divisions/corpfin/cf-noaction/14a-8/2014/michaelweinstein022114-14a8.pdf.

Portfolio & Launch Management at Sandoz, Inc. AHF has informed these companies in writing that it is looking for a generic pharmaceutical maker to "supply[] AHF with a generic version of standalone TAF and supplying AHF with a generic combination therapy that contains TAF as part of an HIV treatment regime (e.g., a generic version of Genvoya)."

34. AHF has informed generic makers, including Teva North America, Autobindo Pharma USA, Lupin Pharmaceuticals, and Sandoz, that it is actively working to bring a generic version of TAF to market to distribute to AHF's clinicians, pharmacies, and patients. In addition, AHF has provided written notice to these same generic pharmaceutical makers that AHF is "ready and able to distribute a generic version of TAF as a standalone compound (that would be used in a combination HIV treatment regime) or a generic tablet containing TAF as part of an HIV therapy."

35. Gilead has not granted AHF's request for a covenant not to sue for a claim that AHFs activities give rise to induced and/or direct infringement of patents relating to TAF. AHF requested in writing that Gilead provide a covenant not to sue AHF arising from AHF's activities in selling, distributing, and offering for sale, generic versions of TAF and HAART therapies that contain TAF as part of a combination formulation.

36. AHF has a reasonable, immediate, and real concern of legal action initiated by Gilead based on the actions of AHF to gain access to a generic version of TAF and Gilead's refusal to grant AHF a covenant not to sue. AHF provided written notice to Brett Pletcher, Executive Vice President and General Counsel at Gilead that:

> AHF intends to manufacture, purchase, import and/or sell tonofovir alafenamide, which Gilead has claimed is subject to patents assigned and/or licensed to Gilead. Based on Gilead's listing of these patents in the Orange Book and numerous other actions by Gilead, the AHF has a reasonable and real anticipation of legal action should it continue to undertake steps toward securing the manufacture, purchase, and importation of tonofovir alafenamide. Further, AHF has been forced to forgo certain activities that it otherwise would have had the capacity and desire to undertake.[14]

37. AHF's activities in bringing generic TAF as an HIV treatment regime were not

[14] Correspondence from AHF to Brett Pletcher of Gilead Science (April 6, 2016).

undertaken merely to assist in the preparation of an Abbreviated New Drug Application ("ANDA") filing. Instead, AHF's activities were undertaken to distribute generic TAF to AHF's clinicians, pharmacies, and patients and extend well beyond the sort of activities that would be included in the preparation of an ANDA filing.

38. Were a generic version of TAF to enter the market this would clearly be considered an act of direct infringement by Gilead. Further, the technology in question is substantially fixed as opposed to fluid and indeterminate at this time. Gilead's patents covering TAF identify TAF as a treatment for HIV, and AHFs actions are directed toward the use of TAF to treat HIV. Gilead and AHF have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

39. AHF's activities are already being impacted by Gilead's actions, including Gilead's orange book listing of patents for Genvoya. For example, the inclusion of a TAF-related patent in the listing for Genvoya will add five years versus four years to the exclusivity period for Genvoya under the listed NCE exclusivity Gilead is claiming for Genvoya. In addition, the patent listings by Gilead include patents that would extend Gilead's exclusivity period for Genvoya until August 15, 2032. AHF has filed this complaint to prevent the following effects that Gilead's activities are already having on AHF, including AHF delaying or forestalling AHF's plans to substantially increase efforts and funding for programs and activities such as:

- Preparing clinicians and patients for treatments that incorporate generic TAF
- Educating the public, government agencies, hospitals, and advocacy organizations about generic TAF
- Working with suppliers to manufacture TAF either as a standalone product to be used in HAART or as part of a combination formulation
- Research activities taken on by scientists
- Preparing for the distribution of HAART therapies incorporating generic TAF
- Conducting investigations regarding the use of generic TAF in HAART therapies

While AHF has undertaken these activities, AHF intends to devote significantly more resources to these activities, but is currently forgoing additional activities based on the threat that Gilead

will assert its patents to TAF. AHF has been forced to suspend plans to distribute generic TAF. Should Gilead's patents to TAF be found invalid, AHF would immediately be able to take the following action: enter into agreements with generic makers regarding the distribution of treatments incorporating TAF; work to identify other combination therapies that incorporate TAF to treat HIV; begin educating the public about generic TAF; preparing clinicians and patients for treatments that incorporate generic TAF.

40. Because of the complexity of treating HIV and adapting HAART therapy for individual patients, AHF's clinicians will tailor and adapt treatments for patients based on the availability of specific drugs that could be years from being released but which are known to be in the pipeline.

41. AHF has a present intent to supply its clients in the United States with TAF drugs including unlicensed TAF drugs and a standalone TAF drug. AHF is prepared to distribute standalone TAF drugs through its network of pharmacies. In addition, AHF has sold Genvoya, which contains TAF obtained from Gilead, to its customers. Further, AHF is ready and immediately able to distribute a standalone version of TAF to its researchers.

42. Gilead has previously entered into pay-for-delay settlements with generic manufacturers. The risk that Gilead will reach a settlement with a generic to delay access is a real and immediate threat. Only through clearing the invalid patents that Gilead has obtained allegedly for TAF will AHF be able to ensure that there is generic entry.[15]

43. At bottom, AHF is in the position of either abandoning its plans and intent to obtain a standalone TAF product or run the risk of being sued for infringement, which is precisely the type of situation the Declaratory Judgment Act is intended to remedy.

44. Gilead's statements regarding its willingness to enforce its intellectual property rights has given AHF a reasonable apprehension that were it to continue its course of obtaining a

[15] Based on a review of court filings it appears that Gilead was able to delay generic entry by reaching settlements in the following two cases. *Gilead Sciences, Inc., v. Teva Pharmaceuticals USA, Inc., et. al*. 1-10-cv-01796 (NYSD Foley Square) (Dkt. No. 128); *Gilead Sciences, Inc., v. CIPLA Limited,* NYSD-1-12-cv-06351 (Dkt. No. 76).

standalone unlicensed version of TAF it would be subject to patent suit by Gilead. These statement include:

> Patents and other proprietary rights are very important to our business. If we have a properly drafted and enforceable patent, it can be more difficult for our competitors to use our technology to create competitive products and more difficult for our competitors to obtain a patent that prevents us from using technology we create. As part of our business strategy, we actively seek patent protection both in the United States and internationally and file additional patent applications, when appropriate, to cover improvements in our compounds, products and technology.[16]
>
> It is the policy of Gilead to enforce its intellectual property rights to the fullest extent permitted under law. Gilead Terms of Use.
>
> Further, Gilead in its License Agreement with Japan Tobacco agreed to investigate any alleged or threatened infringement and assist in the investigation and enforcement "pertaining to such infringement.[17]

45. Gilead has frequently filed suit to enforce its patent rights.[18] Gilead has alleged infringement against companies such as Teva based on its patents relating to Tenofovir.

46. AHF has conducted analysis of some potential combination therapies for HIV that incorporate TAF. These potential therapies include:

Potential Use Of Standalone TAF In Combined Therapy	**Notes Based On NIH Recommendations For Therapy Where TDF Is Used Instead of TAF**
TAF + Emtricitabine + Dolutegravir	Antiretroviral-naive patients & Integrase Strand Transfer Inhibitor-Based Regimens; also potential for Acute And Recent Early HIV Infection - Antiviral Therapy ("ART")
TAF + Dolutegravir + Lamivudine	Antiretroviral-naive patients & Integrase Strand Transfer Inhibitor-Based Regimens
TAF + Emtricitabine + Raltegravir	Antiretroviral-naive patients & Integrase Strand Transfer Inhibitor-Based Regimens
TAF + Raltegravir + Lamivudine	Antiretroviral-naive patients & Integrase Strand Transfer Inhibitor-Based Regimens

[16] Gilead 10-K at 16 (2014).

[17] Third Amendment to License Agreement Between Japan Tobacco and Gilead Sciences § 3.16 (July 5, 2011).

[18] *See e.g., Gilead Sciences, Inc. et al v. Watson Laboratories, Inc.* NJD-1-15-cv-02350 (Filed April 3, 2015).

TAF + Emtricitabine + Ritonavir + Darunavir	Antiretroviral-naive patients & Protease Inhibitor-Based Regimen; also potential for Acute And Recent Early HIV Infection - Antiviral Therapy ("ART")
TAF + Ritonavir + Darunavir + Lamivudine	Antiretroviral-naive patients & Protease Inhibitor-Based Regimen
TAF + Efavirenz + Elvitegravir + Cobicistat + Rilpivirine	Dual NRTI and potential in HIV/HBV Co-infected patients.

47. Otto Yang (Scientific Director for AHF), Michael Wohlfeiler (Chief of Medicine for AHF), and Robert Heglar (Deputy Chief of Medicine for AHF), are conducting an ongoing study of TAF in treating patients. This has included internal reviews of literature regarding TAF in HAART therapies, discussions regarding the efficacy of TAF at internal AHF meetings, and circulating documents relating to preparing for generic TAF and its impacts on treatment regimens. While AHF has undertaken the activities that it has to help expedite the release of generic versions of TAF, particularly a standalone version of TAF, the litigation threat by Gilead has had a chilling effect on AHF being able to continue its investigation and preparation for distributing generic TAF.

48. Taken together, Gilead's activities thus demonstrate that it has engaged in a course of conduct that shows a preparedness and a willingness to enforce its patent rights.

B) Gilead

49. Defendant Gilead is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

50. Gilead is a biopharmaceutical company that develops and commercializes medicines. Its primary areas of focus include human immunodeficiency virus (HIV), liver diseases such as chronic hepatitis C virus (HCV) infection and chronic hepatitis B virus (HBV) infection, oncology and inflammation, and serious cardiovascular and respiratory conditions.

51. Sales of Gilead products, including sales related to HIV and liver diseases were $22.8 billion in 2014, $9.3 billion in 2013 and $8.1 billion in 2012. This represented 91% of

Gilead's total revenues in 2014, 83% of Gilead's total revenues in 2013, and 84% of Gilead's total revenues in 2012. Gilead sales through the first three quarters of 2015 were an astonishing $23.7 billion putting them on pace for yearly sales of over $30 billion for the entire year.

52. Gilead notes in its SEC filings, one of the primary risks the company faces is that, "[a] substantial portion of [its] revenues is derived from sales of products to treat HCV and HIV. If [Gilead is] unable to maintain or continue increasing sales of these products, [the] results of operations may be adversely affected." In fact, for the year ended December 31, 2014, sales of its HIV products accounted for more than 40% of total product sales. Most of Gilead's HIV products contain tenofovir disoproxil fumarate and/or emtricitabine, which belong to the nucleoside class of antiviral medications.

53. Gilead publicly acknowledges that if the treatment paradigm for HIV changes, causing nucleoside-based therapeutics to fall out of favor, or if Gilead is unable to maintain or continue increasing its HIV product sales, Gilead's profits would suffer. Gilead acknowledged that it might not be able to sustain or increase the growth rate of sales of HIV products if generic HIV products are introduced into major markets because its ability to maintain pricing and market share may be affected. Gilead therefore has resorted to new patent strategies to stop generic HIV products from eroding its enormous profits.

54. Gilead's pricing is unrelated to its expenditures on Research and Development.

55. Gilead has litigated on patents relating to Tenofovir.

56. Gilead owns the following patents:

- U.S. Patent No. 7,390,791, entitled "Prodrugs of phosphonate nucleotide analogues."
- U.S. Patent No. 7,803,788, entitled "Prodrugs of phosphonate nucoleotide analogues."

U.S. Patent No. 8,148,374, entitled "Modulators of pharmacokinetic properties of therapeutics."

U.S. Patent No. 8,754,065, entitled "Tenofovir alafenamide hemifumarate."

57. Gilead pursued patents on TAF despite publically claiming that it was discontinuing its development programs for TAF. On October 21, 2004, Gilead's CEO John C.

Martin announced, "the company is discontinuing its development programs for GS 9005 and GS 7340, two investigational products for the treatment of HIV." *Gilead Discontinues Development of GS 9005 and GS 7340; Company Continues Commitment to Research Efforts in HIV*, GILEAD PRESS RELEASE (October 21, 2004).

58. Despite its public statements that it was abandoning development of TAF, from October 22. 2004 to May 20, 2005, Gilead filed seven patent applications relating to the use of TAF treat HIV. These patent applications included:

- U.S. Patent App. 10/970,389 (Filed October 22, 2004) (This patent application was issued as U.S. Patent No. 7,273,716 and is one of the Orange Book listed patents for Genvoya).
- European Patent App. 2004/0816931 (Filed October 22, 2004) (This was concurrently with the World International Property Organization or WIPO. A copy of the WIPO Application is attached).
- European Patent App. 2004/0817046 (Filed December 22, 2004).
- U.S. Patent App. 11/031,250 (Filed January 6, 2005) (The application states: "After 1 hour, GS-7340 results in 10>< and 30x the total intracellular concentration of PMPA species in PBMCs as compared to TDF and PMPA, respectively." "As shown, nelfinavir and GS-7340 are 2-3 orders of magnitude more potent than all other nucleotides or nucleosides.").
- U.S. Patent App. 11/031,251 (Filed January 5, 2005).
- U.S. Patent App. 11/031,252 (Filed January 6, 2005).
- U.S. Patent App. 11/031,228 (Filed January 6, 2005).
- U.S. Patent App. 11/133,463 (Filed May 20, 2005) (this patent application was issued as U.S. Patent No. 8,633,219 and was assigned to Japan Tobacco which has licensing and research agreements with Gilead relating to TAF and other HIV Drugs).

59. In 2005, Gilead researchers published papers and delivered talks on the efficacy of using TAF to treat HIV. These included a June 27, 2005 presentation from Dr. Arnold Fridland and William Lee entitled, "Lymphatic Targeting of Tenofovir; Intracellular Pharmacokinetics and Viral Dynamics." The presentation concluded with a slide stating that "GS-7340-02 produces rapid achievement of high concentrations of GS-7340 in the plasma." A May 2005 article from William Lee (of Gilead) finding "In conclusion, the high concentrations of tenofovir observed in lymphatic tissues after oral administration of GS 7340 are expected to result in increased clinical

potency relative to tenofovir DF and could have a profound effect on the low-level virus replication that occurs in tissues with suboptimal drug exposure during HAART.") William Lee, *Selective Intracellular Activation of a Novel Prodrug*, in ANTIMICROBIAL AGENT AND CHEMOTHERAPY p. 1898-1906 (May 2005).

C) Japan Tobacco Inc., Japan Tobacco International U.S.A., Inc., and Akros Pharma Inc.

60. Defendant Japan Tobacco, Inc. is a corporation organized under the laws of Japan, having a principal place of business at 2-1, Toranomon 2-chome, Minato-ku, Tokyo 105-8422.

61. Defendant Japan Tobacco International U.S.A., Inc. is a corporation organized under the laws of the State of California, having a principal place of business at 500 Frank W. Burr Boulevard, Suite 24, Teaneck, New Jersey.

62. Defendant Akros Pharma Inc. is a corporation organized under the law of the State of New York, having its principal place of business at 302 Carnegie Street Suite 300, Princeton, New Jersey 08540. Akros Pharma Inc. has identified its agent of service as the Corporation Service Company and can be served at Corporation Service Company – Lawyers Incorporating Service, 2710 Gateway Oaks Drive Suite 150N, Sacramento California 95833.

63. Akros Pharma Inc. identifies its mission as "To realize commercial and strategic opportunities for JT [Japan Tobacco], through active licensing and the formation of new collaborative alliances with partners in areas ranging from the laboratory to the clinic."[19] In addition, Akros Pharma identifies that it works with companies such as Gilead to "maximize" the "commercial potential" of Japan Tobacco pharmaceutical patents.[20]

64. Akros Pharma identifies that it is in an alliance with Gilead to license emtricitabine for use in HIV treatments.

[19] *Akros Mission*, AKROS PHARMA WEBSITE (last visited April 2016), available at: http://www.akrospharma.com/corp-amission.htm.

[20] *Id*.

Alliances

COMPANY	Product/Compound	Mechanism	ARRANGEMENT
Pfizer	Viracept®	HIV Protease Inhibitor	In-License
Toray	REMITCH® (Narfurafine Hydrochloride)	κ-opioid Receptor Agonist	In-License
Gilead Sciences	Viread® (Tenofovir Disoproxil Fumarate)	HIV RTI	In-License
	Emtriva® (Emtricitabine)	HIV RTI	In-License
	Truvada®	Co-formulation of the two products, Viread® and Emtriva®	In-License
	Cobicistat	PK enhancer	In-License
	JTK-303 (Elvitegravir)	Integrase Inhibitor	Out-License

Akros Pharma Alliances, AKROS WEBSITE (last visited April 2016), available at: http://www.akrospharma.com/pipe-alliances.htm.

65. Japan Tobacco, Inc. Japan Tobacco International U.S.A., Inc., and Akros Pharma, Inc. (collectively, "Japan Tobacco") entered into a series of exclusive licensing agreements with Gilead relating to the compound elvitegravir.

> In 2005, we entered into a licensing agreement with Japan Tobacco, under which Japan Tobacco granted us ***exclusive rights to develop and commercialize elvitegravir***, a novel HIV integrase inhibitor, in all countries of the world, excluding Japan, where Japan Tobacco retains such rights.[21]
>
> The agreement and our obligation to pay royalties to Japan Tobacco will terminate on a product-by-product basis as patents providing exclusivity for the product expire or, if later, on the tenth anniversary of the commercial launch for such product.[22]

66. The agreement between Japan Tobacco, Inc. and Gilead Sciences is defined in the definitions section of the 2011 Third Amendment to the License Agreement as covering Japan Tobacco and its affiliates. "'Japan Tobacco' shall mean Japan Tobacco Inc., a Japanese corporation, and its affiliates."[23] Thus, Akros Pharma, Inc. and Japan Tobacco International U.S.A., Inc. are parties to the agreement which licenses the subject patents to Gilead.

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[21] Gilead Sciences 10-K at 12 (2014) (emphasis added).

[22] Gilead Sciences 10-K at 12 (2014).

[23] GILEAD SCIENCES THIRD AMENDMENT TO THE LICENSE AGREEMENT BETWEEN JAPAN TOBACCO AND GILEAD SCIENCES (July 5, 2011).

67. Further, Gilead treats Japan Tobacco and its subsidiaries (such as Akros Pharma, Inc. and Japan Tobacco International U.S.A., Inc.) as being a combined entity by extending to all of Japan Tobacco's subsidiaries and affiliates indemnification protection for any disputes arising out of the agreement.

> ***Gilead hereby agrees to Indemnify JT and its Affiliates***, agents, directors, officers and employees (the "JT Indemnitees") from and against any and all Losses resulting from Third Party Claims arising directly or indirectly out of (i) a breach of any obligations of Gilead under this Agreement, including without limitation Gilead's representation and warranties or covenants pursuant to Article 10; or (ii) the Development, manufacture (to the extent of any formulation work performed by Gilead pursuant to Article 7), storage, distribution, promotion, labeling, handling, use, sale, offer for sale or importation of Compound and/or Products by Gilead, its Affiliates or its Generic Licensees in the Gilead Territory (subject to Section 11.3).[24]

68. Japan Tobacco holds itself out in statements to the public as a unified entity that conducts itself across its subsidiaries and affiliates. "Stakeholder engagement across the JT Group is conducted under our '4S' model, which requires us to balance the interests of four stakeholder groups."[25]

69. Japan Tobacco's website identifies its work in developing pharmaceutical products and selling cigarettes to consumers world-wide. Further, Japan Tobacco holds itself and its subsidiaries out as a unified entity referred in Japan Tobacco's own documentations, websites, financial reports, and statements to regulators as the "JT Group." "The JT Group operates diverse businesses across the tobacco, pharmaceutical, and processed food sectors. Our business is global, extending to Europe, CIS countries, Africa, the Middle East, Asia and Americas."[26]

70. Japan Tobacco owns the following patents, which it has licensed to Gilead:

- U.S. Patent No. 7,176,220, entitled "4-oxoquinoline compound and use thereof as pharmaceutical agent."
- U.S. Patent No. 7,635,704, entitled "Stable crystal of 4-oxoquinoline compound."

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[24] *Id*. at 7 (emphasis added).

[25] JT GROUP SUSTAINABILITY REPORT at 16 (2013) (referring to the JT Group engagement of shareholders, consumers, employees, and society).

[26] *Japan Tobacco Company Overview*, JAPAN TOBACCO WEBSITE (last visited April 2016), available at: https://www.jt.com/about/outline/index.html.

- U.S. Patent No. 8,633,219, entitled "Combination therapy."
- U.S. Patent No. 8,981,103, entitled "Stable crystal of 4-oxoquinoline compound."

D) Johnson & Johnson, Inc. and Janssen Sciences Ireland UC

71. Defendant Johnson & Johnson, Inc. is a corporation organized under the laws of the State of New Jersey, with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

72. Defendant Janssen Sciences Ireland UC is a corporation organized under the laws of Ireland, with its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland. Defendant Janssen Sciences Ireland UC is a subsidiary of Johnson & Johnson, Inc. (Janssen Sciences Ireland UC and Johnson & Johnson, Inc. are collectively referred to herein as "Janssen").

73. Janssen has licensed the use of rilpivirine to Gilead for its inclusion in Odefsey. Under the terms of Gilead's license with Janssen, the "parties share revenue based on the ratio of set selling prices of the party's component(s)" with Gilead retaining "a specified percentage of Janssen's share of revenues, up to 30% in major markets." GILEAD SCIENCES 2015 10-K at 12 (2015). Thus, Gilead's inclusion of rilpivirine in Odefsey enables Gilead to earn profits by tying sales of TAF to rilpivirine.

III. JURISDICTION AND VENUE

74. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. § 1331, § 1337(a), and § 1338, based on Defendants' anticompetitive conduct, and the existence of an actual controversy between AHF, on the one hand, and Defendants, on the other hand, for claims under the Patent Laws. *See infra*.

75. This Court further has supplemental jurisdiction over Plaintiff's claims under Plaintiff's causes of action pursuant to California and Nevada law pursuant to 28 U.S.C. §§ 1332(d) and 1367 because the claims arise from the same nucleus of operative facts as the federal antitrust law claims.

76. This Court has personal jurisdiction over Defendants pursuant to the laws of the State of California, including California's long-arm statute, and California Code of Civil Procedure § 410.10. First, the Court has jurisdiction over Gilead which is, on information and belief, the direct owner of each of the Patents-in-Suit because Gilead maintains its principal place of business in this district and because Gilead is registered with the California Secretary of State to do business in California.

77. The Court also has personal jurisdiction over each of the Defendants because each of the Defendants has purposely conducted its patent enforcement activities in this district and towards residents of this District. These enforcement activities include the signing of agreements regarding the exclusive licensing of patents that are orange book listed for Genvoya.

78. Venue is proper in this Court pursuant to 15 U.S.C. § 22 and 28 U.S.C. §§ 1391 and 1400 because Gilead resides in the Northern District of California[27] and a substantial portion of the events giving rise to this action, including the development of the accused instrumentalities, took place here.

IV. REGULATORY BACKGROUND

79. Gilead uses patents of dubious validity to inflate the prices of a compound discovered over 31 years ago - well outside traditional patent protection.

80. Brand drug companies like Gilead often obtain valid patents that cover the new drug products. This process encourages research and development of new drugs by providing a time-limited period wherein the brand drug company is the only company that can distribute the new product.

81. This period of time (20 years) is limited to the statutory term of the patent covering the new drug. Once the patents expire, other companies are free to make their own versions of the same products, ushering in competition that lowers prices for consumers of the prescription drugs.

[27] On average, it takes 2.7 years from filing of a patent complaint to adjudication at trial in the Northern District of California. 2015 PATENT LITIGATION STUDY – PWC at 15 (2015).

82. Given the high profits brand drug companies can reap while a drug is under patent protection, brand drug companies develop sophisticated patent prosecution strategies to try to maximize the time during which they are the sole distributors of the drug in question.

A) Brand Drug Company Patent Strategy

83. In many cases, the first group of patents covering a new brand drug reflect a genuine technological breakthrough that will provide the backbone of a new, safe, and effective drug. These initial patents typically cover the active compound in a prescription drug or a particular pharmaceutical composition.

84. With respect to TAF, the prodrug compound was not a breakthrough and should not have been patentable. At the time TAF was developed it was well known that formulating antiviral compounds as prodrugs allows intracellular absorption. Thus, substituting the disoproxil ester of Tenofovir with an aryl phosphoramidate ester would have been obvious. Similarly, the use of fumarate salt for formulation purposes would be obvious in light of TDF and the other considerable prior art on salt selections.

85. As the research and development process on the drug continues, a brand drug company will continue filing patent applications with the United States Patent and Trademark Office. However, the initial breakthrough is already in the prior art – either because the brand drug company has already filed a patent application on it or, like here, the brand drug company is working to commercialize previous scientific breakthroughs. Therefore, the follow-on patents prosecuted by brand drug companies are limited in scope. These follow-on patents can only be obtained for features of the drug that the brand drug company can show are non-obvious improvements over the growing body of prior art.

86. A typical patent portfolio for a brand drug has its most significant patent issuing first. The later follow-on patents are typically much weaker and more vulnerable to attack as invalid under either 35 U.S.C. §§ 102 and/or 103 as anticipated or obvious in view of older subject matter in the prior art. Many times the these follow-on patents merely claim methods of using compounds and formulations that are known in the prior art and are thus vulnerable to invalidation

under 35 U.S.C. § 101 for claiming patent ineligible subject matter. These follow-on patents are also often easy to design around, and thus not infringed by competitors interested in entering the market.

87. While follow-on patents are often fairly weak, brand drug companies pour extensive resources into obtaining these patents because the later-issued patents extend the period of time their drugs are covered by unexpired patents. That is, because the follow-on patents are typically filed much later than the earlier patents, their expiration dates fall later than the expiration dates of the earlier patents. This strategy of continually filing follow-on patents is commonly described as "ever-greening."

B) FDA Approval of New Drugs

88. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a brand drug manufacturer obtains FDA approval to market a new drug by filing a New Drug Application ("NDA").[28] The NDA process is a long and expensive process requiring multiple phases of clinical trials. It can take anywhere between 7-17 years to conduct the clinical trials necessary to obtain the scientific evidence necessary to obtain approval of an NDA.[29] Throughout the NDA process, the brand drug maker aims to provide the FDA with data establishing that the drug is safe and that it is effective in treating the conditions identified in the proposed labeling of the new drug.

C) FDA "Orange Book"

89. To place other drug makers on notice about potential proprietary patent claims for newly-approved drugs, a brand drug maker must identify to the FDA all patents it believes cover its new drug. The FDA publishes a list of those patents' corresponding brand drugs in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is commonly referred to as the "Orange Book."

90. Patents that are issued after the FDA approved an NDA for a new drug may be

[28] 21 U.S.C. §§ 301-392.

[29] *See, e.g.*, http://www.fdareview.org/approval_process.shtml

listed in the Orange Book within 30 days of a new patent's issuance.

91. Under FDA rules, the brand drug maker is only permitted to list patents that are "reasonably enforceable." However, there is no FDA review or oversight as to whether any particular listing of a patent corresponding to a brand drug is "reasonably enforceable" or appropriate. The FDA merely relies on the drug maker's truthfulness about patent validity and applicability. The FDA only performs a ministerial act in listing the patents identified by drug makers in the Orange Book.

D) Approval Process for Generic Drugs

92. In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were designed to speed introduction of low-cost generic drugs to market by permitting manufacturers of generic drugs to file an abbreviated new drug application ("ANDA"). The ANDA process allows the generic drug manufacturer to rely on the scientific data regarding safety and efficacy the brand drug maker submitted in its NDA. In the ANDA, a generic manufacturer need only show that the generic drug is pharmaceutically equivalent and bioequivalent to the brand drug.

93. Because the ANDA process does not require the multiple phases of clinical trials required by the NDA process, generic drug manufacturers can gain FDA approval to market a generic version of the brand drug much faster and less expensively than if they had to conduct their own clinical trials.

94. The purpose of the Hatch-Waxman Amendments was to speed the entry of safe and effective generic versions to market so that the public could enjoy the significant cost savings generated by competition in the market for a specific drug.

95. In addition to the streamlined ANDA process, the Hatch-Waxman Amendments created a mechanism to resolve patent disputes between brand and generic manufacturers before generic products launch. The Hatch-Waxman Amendments permit a brand manufacturer to sue a generic manufacturer for patent infringement even if the ANDA has not yet been approved and the generic version of the drug introduced on the market.

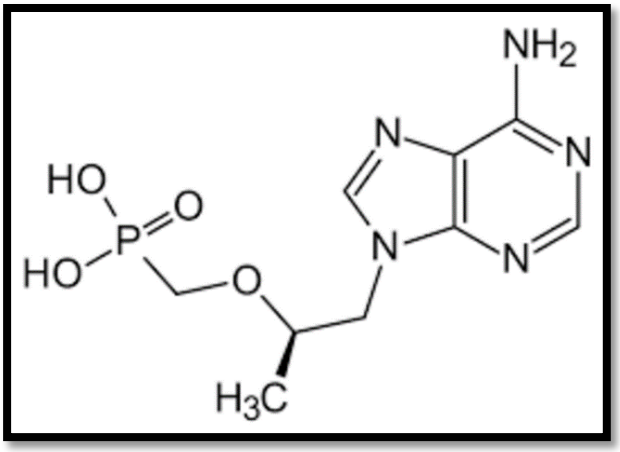
96. When a manufacturer files an ANDA application, the generic manufacturer must certify that the proposed generic drug will not infringe any valid patent listed for the brand drug in the Orange Book. The generic manufacturer can make one of four certifications: (i) that no patent for the brand drug has been filed with the FDA; (ii) that the patent for the brand drug has expired; (iii) that the patent for the brand drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or (iv) that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

97. If a generic manufacturer files a Paragraph IV certification, a brand drug maker can sue the ANDA applicant for patent infringement immediately – the brand drug maker does not need to wait for the generic version of the drug to enter the market. If the brand drug maker files an infringement action against the ANDA applicant within 45 days of receiving notification of the Paragraph IV certification ("Hatch-Waxman Litigation"), the FDA cannot grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA will not authorize the generic manufacturer to market its generic drug.

V. FACTUAL ALLEGATIONS

A) The Development Of Tenofovir

98. Tenofovir was first discovered more than three decades ago by researchers in the Czech Republic. Tenofovir was initially synthesized by Antonín Holý at the Institute of Organic Chemistry and Biochemistry, Academy of Sciences of the Czech Republic in Prague. From early on, it was clear that tenofovir exhibited anti-HIV effects. However, the initial form of tenofovir used in these studies had limited potential for widespread use because it was not absorbed when administered orally.



Tenofovir Molecular Structure.

99. In 1997, Gilead obtained a patent on a prodrug formulation of tenofovir that allowed absorption of tenofovir in the gut. The formulation of prodrugs was well known at the time as was the anti-HIV effectiveness of tenofovir. By combining the known technique "ProDrug Formulation" to an existing compound with anti-HIV properties, tenofovir disoproxil (TDF) was developed.

100. The patent application filed by Gilead on tenofovir was originally rejected on obviousness grounds – both compounds were known, as was the fact that conversion of a compound to its salt could enhance activity. Unless it could be shown that the salt possessed unexpected properties, it was unpatentable. The applicant replied that the salt did indeed possess unexpected properties – it had greater stability at higher humidity and temperature levels. On this basis, a patent was granted in August 1999. This history underscores the dubious nature of the prodrug patents on tenofovir.

101. TDF was approved by the U.S. FDA on October 26, 2001, for the treatment of HIV.

1) Gilead Patents Another ProDrug Formulation Of Tenofovir - Tenofavir Alafenamide (TAF)

102. GS-7340, or TAF, is a prodrug of tenofovir. TAF is taken orally and after absorption, it passes into the blood. From the blood, TAF is absorbed by cells of the immune system and converted into tenofovir.

103. The purported inventive step in TAF appears to be the simple process of combing well known techniques in prodrug formulation with the tenofovir compound that had been known for over a decade as having anti-HIV effects.

104. Commentators reviewing the TAF patents have found them weak. .Doctors Without Borders, in its publication, explained, "The main patent is potentially weak and can be opposed in countries where patent opposition systems are functional."[30]

105. Instead of developing a standalone drug product, Gilead, based on the weakness of the patents on TAF, went forward with a pharmaceutical drug product combining four active ingredients: 150mg cobicistat, 150mg elvitegravir, 200mg emtricitabine and EQ 10mg base tenofovir alafenamide fumerate. Three of these active ingredients were licensed by Gilead from third parties. By bundling TAF into a combination product with other patentable active ingredients, Gilead was able to list twelve patents as covering the combined drug formulation in the Orange Book. The below image shows the Orange Book listed patents for this combined drug – Genvoya.

Patent Data

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code	Delist Requested
N207561	001	5814639	Sep 29, 2015	Y	Y		
N207561	001	5814639*PED	Mar 29, 2016				
N207561	001	5914331	Jul 2, 2017	Y			
N207561	001	5914331*PED	Jan 2, 2018				
N207561	001	6642245	Nov 4, 2020			U - 257	
N207561	001	6642245*PED	May 4, 2021				
N207561	001	6703396	Mar 9, 2021	Y	Y		
N207561	001	6703396*PED	Sep 9, 2021				
N207561	001	7176220	Nov 20, 2023	Y	Y	U - 257	
N207561	001	7390791	May 7, 2022	Y	Y		
N207561	001	7635704	Oct 26, 2026	Y	Y	U - 257	
N207561	001	7803788	Feb 2, 2022			U - 257	
N207561	001	8148374	Sep 3, 2029	Y	Y	U - 1279	
N207561	001	8633219	Apr 24, 2030		Y	U - 257	
N207561	001	8754065	Aug 15, 2032	Y	Y	U - 257	
N207561	001	8981103	Oct 26, 2026	Y	Y		

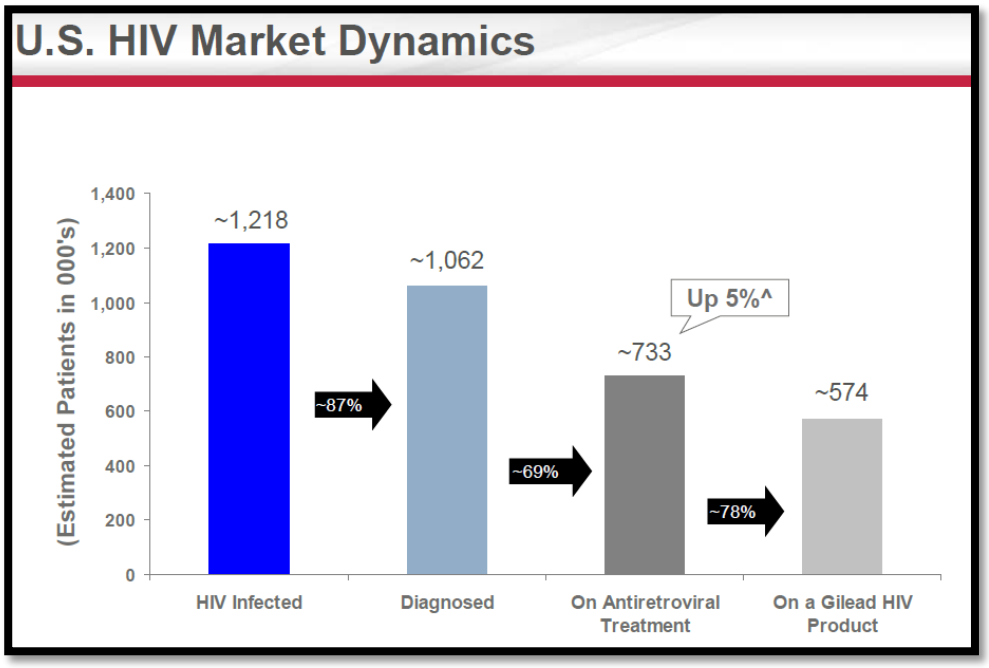
Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
N207561	001	NCE	Nov 5, 2020

[30] MEDECINS SANS FRONTIERES REPORT (July 2013), available at: https://www.msfaccess.org/sites/default/files/AIDS_Report_UTW16_ENG_2013.pdf.

106. The techniques Gilead undertook to transform the base tenofovir compound into an end formulation were obvious in light of existing literature and knowledge on how to formulate poorly bioavailable nucleotide analogs.

107. A core goal of Gilead is to move HIV infected individuals onto its Gilead HIV Products. The below chart from Gilead's most recent earnings release shows the process of moving individuals diagnosed with HIV to a Gilead Product.



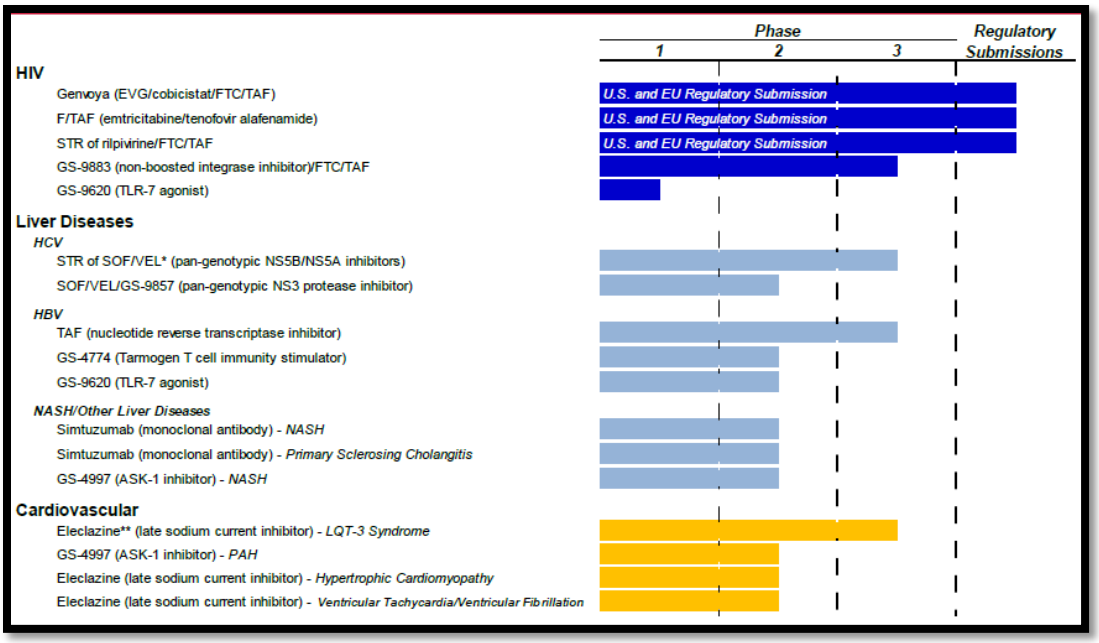
GILEAD 2015 THIRD QUART EARNINGS SLIDES at 29 (2015).

108. The co-formulation of Genvoya blocks lower priced generic entry and artificially inflates pricing. Analysts have confirmed that the failure to provide a standalone product harms the public.

> Innovator companies must ensure that novel compounds are studied and made available on the market as single pills as well as in fixed-dose combinations (FDCs) to enable people with HIV to assemble optimal combinations based on their own needs. Thus, Gilead needs to ensure that elvitegravir, cobicistat, and – when available – tenofovir alafenamide (TAF) are each available as single pills to maximize patient and provider choice. This is particularly critical for TAF.[31]

[31] 2013 PIPELINE REPORT at 40 (June 2013) (report published by HIV advocacy organizations HIV i-Base and Treatment Action Group).

109. Despite this harm from releasing only combination drugs, Gilead has only combination drugs in its pipeline for drugs incorporating TAF.



Gilead Third Quart Earnings Slides at 6 (October 27 2015) (Four of five Gilead HIV Drugs that are in the pipeline are combination drugs that include TAF.).

2) Artificially High Pricing For Drugs Such As Genvoya, Odefsey, and Descovy Harms The Public And Allows Gilead To Wrongfully Reap Billions In Profit.

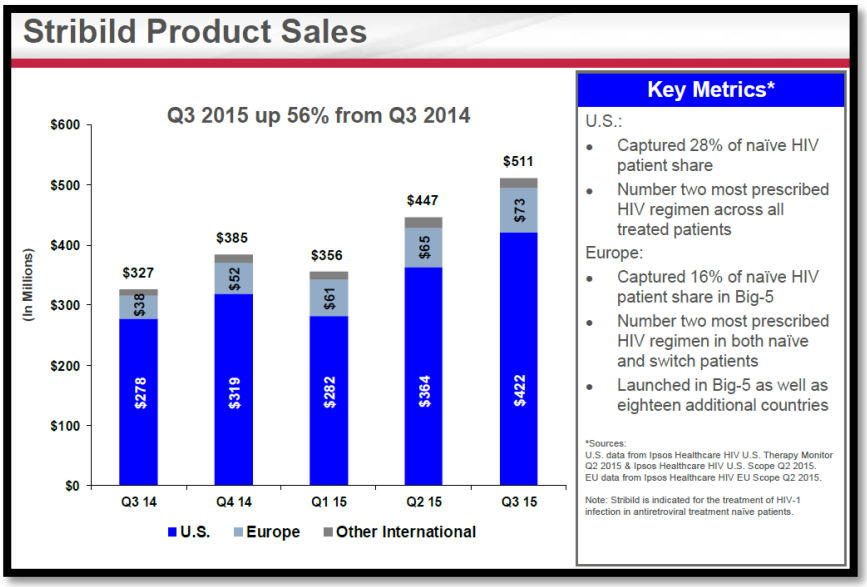
110. In stark contrast to the wealth of Gilead, people living with HIV and AIDS (those most desperately in need of Gilead's medications) are among the poorest and most vulnerable in the United States. Gay, bisexual, and other men who have sex with men (MSM) of all races and ethnicities remain the population most profoundly affected by HIV. Although MSM represent about 4% of the male population in the United States, in 2010, MSM accounted for 78% of new HIV infections among males and 63% of all new infections. MSM accounted for 54% of all people living with HIV infection in 2011, the most recent year these data are available.

111. Moreover, African Americans continue to experience the most severe burden of HIV compared with other races and ethnicities while Hispanics/Latinos are also disproportionately affected by HIV. African Americans, who make up just 12% of the population, account for 44% of new infections.

112. Economic status often determines access to HIV treatment and individuals with

low status have delayed treatment initiation relative to more affluent patients, reducing their chances of survival. Nearly 90% of Ryan White HIV/AIDS Program clients – clients receiving federal funds for HIV/AIDS care and treatment – have a household income of less than 200% of the Federal Poverty Level (about $23,000). Despite the link among income/HIV status/access to treatment, Gilead continues to put profits ahead of patients.

113. Gilead's Stribild Product Sales were over one billion dollars in the first three quarters of 2015.



GILEAD 2015 THIRD QUART EARNINGS SLIDES at 32 (2015).

114. Through its patent schemes, Gilead is able to earn outsized profit margins. For example, in the third quarter of 2015 Gilead's Non-GAAP Product Gross Margin was nearly 90%. This money is paid by organizations such as AHF that are harmed by invalid patents that artificially prop up the pricing of branded drugs like Genvoya, Odefsey, and Descovy.

115. Gilead's tactics themselves harm AHF. For example, Gilead refuses to release a standalone version of TAF and thus prevents AHF from providing efficient treatment options that are tailored to its patients. The World Health Organization has identified Gilead's tactic as harmful.

> TAF is being co-formulated with emtricitabine (FTC), elvitegravir and cobicistat and is being trialled in phase III now. In order for TAF to reach its full impact,

> registration that includes flexibility in its use and ability to be combined with other ARVs is required. As such, TAF should be registered as a single drug.[32]

116. AHF Research has nearly 20 years of experience with anti-retroviral (ARV) studies and is dedicated to discovering better treatments and improving quality of life for people living with HIV. However, by preventing AHF from studying the efficacy of a standalone version of TAF, Gilead harms AHF's research endeavors.

117. AHF's Pharmacies have been directly harmed by Gilead's patent thicket. AHF operates 37 Pharmacies in 11 states. AHF Pharmacies include locations in this District: 4071 18th St., San Francisco, CA 94114 and 400 30th St. Suite 300, Oakland, CA 94609. Granting access to TAF directly will lead to a direct increase in access to drugs. Indeed, following widespread pressure from groups taking issue with Gilead's prior activities relating to drug pricing, Gilead granted the Medicines Patent Pool (MPP) the "right to sub-license TAF to generic drug companies who manufacture and distribute in 112 developing countries."[33]

B) Gilead's Scheme To Block Competition And Monopolize The Market For TAF.

1) Monopoly Power And Market Definition.

118. At all relevant times, Gilead has maintained monopoly power over tenofovir alafenamide ("TAF") in that it has the power to maintain the price of TAF at supracompetitive levels without losing so many sales as to make the supracompetitive price unprofitable. Gilead readily admits its monopoly power over TAF: "Gilead received five years of regulatory exclusivity, running to at least November 2020, during which no generic form of TAF can be approved by the FDA ('NCE exclusivity')."[34] Gilead further states that its NCE exclusivity "prevents anyone from filing for FDA approval of any version of TAF until late 2019 . . . ."[35]

119. Direct proof exists that Gilead has monopoly power over the price of TAF. Such

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[32] Untangling the Web of ARV Price Reductions, World Health organization at 17, https://www.msfaccess.org/sites/default/files/MSF_UTW_17th_Edition_4_b.pdf.

[33] GILEAD 2015 THIRD QUARTER SLIDES at 48 (2015).

[34] *AIDS Healthcare Foundation, Inc. v. Gilead Sciences, Inc., et al.*, Case No. 3:16-cv-004433-WHA, Dkt. No. 29, at 1 (N.D. Cal. March 21, 2016).

[35] *Id.* at 9.

direct evidence includes, among other things, the abnormally high price margins enjoyed by Gilead and Gilead's ability to profitably maintain the price of TAF well above competitive levels.

120. To the extent Plaintiff is legally required to prove monopoly power circumstantially by first defining a relevant product market, the relevant product market is all TAF-containing products. The relevant geographic market is the United States and its territories.

121. A small but significant non-transitory price increase above the competitive level for TAF by Gilead would not cause a loss of sales sufficient to make the price increase unprofitable.

122. At competitive price levels, TAF does not exhibit significant positive cross-elasticity of demand with respect to price with any other products.

123. TAF's pharmacological profile, and thus its side effects and efficacy profile, is different from other medicines used to treat the same or similar conditions. For example, TAF has lower incidence of impaired kidney function than tenofovir disoproxil. These differences play a critical role in doctors' selection of the most appropriate treatment for patients. Other, non-TAF-containing medicines cannot be automatically substituted for the only TAF-containing products (Genvoya, Odefsey, and Descovy) on the market by pharmacists. Other medicines do not exhibit substantial cross-price elasticity of demand with respect to TAF, and thus are not economic substitutes for, nor reasonably interchangeable with, TAF.

124. The existence of other products designed to treat HIV have not significantly constrained Gilead's pricing of Genvoya, Odefsey, and Descovy (its only TAF-containing products in the relevant market). Gilead has never lowered the price of Genvoya, Odefsey, or Descovy in response to the pricing of other branded treatments.

125. Gilead needed to control only Genvoya, Odefsey, and Descovy, and no other products, in order to maintain the price of TAF profitably at supracompetitive prices. Only the market entry of a generic versions of TAF-containing products and/or a TAF stand-alone product would render Gilead unable to profitably maintain its current prices of Genvoya, Odefsey, and Descovy without losing substantial sales.

126. Gilead has maintained and exercised the power to exclude and restrict competition to TAF.

127. At all relevant times, Gilead's market share in the relevant market was and remains 100%, constituting substantial monopoly power.

2) Interstate Commerce.

128. At all material times, Gilead manufactured, promoted, distributed, and sold substantial amounts of TAF in continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

129. At all material times, Gilead transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of TAF.

130. In furtherance of its efforts to monopolize and restrain competition in the market for TAF, Gilead employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of Gilead were within the flow and have substantially affected interstate commerce.

131. On information and belief, in a conspiracy with its "Authorized Distributors," Gilead has orchestrated a scheme to maintain the artificially high prices of its TAF-containing products by: (1) limiting competition and refusing to sell to distributors or parties capable of directly distributing its products to patients (such as AHF), (2) directly controlling its Authorized Distributors' actions relating to the sale of TAF-containing products through a series of commercial agreements, and (3) reaching tacit agreement to maintain the exorbitant pricing of TAF-containing products.

132. On information and belief, Gilead intentionally keeps the number of "Authorized Distributors" small in an effort to minimize price competition and to incentivize these distributors to not raise antitrust challenges relating to Gilead's business activities. The Authorized Distributors, therefore, tacitly agree and consciously commit to maintain monopoly pricing. By raising challenges as to Gilead's illegal antitrust activities, the Authorized Distributors risk losing

their status as one of the few distributors of highly-profitable products.

133. Because of the small number of authorized distributors and terms on which Gilead sells its pharmaceutical products the margins earned by distributors are very limited. For example, McKesson in its annual report stated "We operate in a highly competitive environment in the distribution of pharmaceuticals and related healthcare services . . . . In the Pharmaceutical segment, we compete with wholesale distributors with national reach (including McKesson Corporation and AmerisourceBergen Corporation)."[36] Price increases are passed directly from Gilead onto AHF.

134. Gilead although claiming roughly 20 authorized distributors, distributes nearly all its pharmaceutical products through three distributors. "In the six months ended June 30, 2015, approximately 89% of our product sales in the United States were to three wholesalers, AmerisourceBergen Corp., McKesson Corp. and Cardinal Health, Inc."[37]

135. Gilead controls its authorized distributors through inventory management agreements that authorized distributors are required to enter.

> Gilead has agreed to pay the wholesalers a fee in exchange for product distribution and inventory management services, market research information, return goods processing assistance and counterfeit product detection services. Additionally, under the terms of the agreements, each wholesaler has agreed not to exceed specified maximum levels of inventory on hand.[38]

136. On information and belief, Gilead's authorized distributors have acted as de facto agents of Gilead, serving no realistic market function except to serve as phantom middlemen in the distribution scheme. Specifically, Gilead's drug discounting programs and other pricing programs mean that Gilead sets a fixed margin that its authorized distributors make when the price paid by AHF and others is set by Gilead. "For qualified programs that can purchase our products through wholesalers or other distributors at a lower contractual price, the wholesalers or distributors charge back to us the difference between their acquisition cost and the lower

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[36] CARDINAL HEALTH INC. FORM 10-K at 30 (August 13, 2015).

[37] GILEAD SCIENCES FORM 10-Q at 41 (August 5, 2015).

[38] *Gilead Signs Inventory Management Agreements with the Three Major U.S. Wholesalers*, GILEAD PRESS RELEASE (July 12, 2004).

contractual price."[39]

137. On information and belief, distributor fees that are paid by Gilead to its authorized wholesalers are of the sort that authorized distributors make a fixed margin set by Gilead and are not acting as a middleman. "Under our inventory management agreements with our significant U.S. wholesalers, we pay the wholesalers a fee primarily for the compliance of certain contractually determined covenants such as the maintenance of agreed upon inventory levels. These distributor fees are based ***on a contractually determined fixed percentage of sales***."[40] Gilead 10-K at 72 (February 24, 2016).

138. On information and belief, authorized distributors are governed by agreements with Gilead that prevent them from filing suit against Gilead. Although the agreements between Gilead and its authorized distributors are not available to the public, Gilead's agreements with generic makers such as Cipla contain arbitration clauses that would prevent a generic maker from filing suit against Gilead in a court. The agreement between Gilead and Cipla contains the following clause. "All disputes arising out of or in connection with the present Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three arbitrators."[41]

3) Effects On Competition.

139. Typically, generic versions of brand drugs are initially priced significantly below the corresponding brand drug. As a result, upon generic entry, purchases of brand drugs are rapidly substituted by purchases of generic versions of that drug. As more generic manufacturers enter the market, prices for generic versions of a drug plunge even further because of the competition among the generic manufacturers, and the brand drug continues to lose even more market share to the generics.

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[39] GILEAD SCIENCES FORM 10-K at 58 (February 24, 2016).

[40] *Id*. at 72 (emphasis added).

[41] GILEAD-CIPLA LICENSE AGREEMENT § 12.7 (September 25, 2014); *see also* GILEAD HCV LICENSE AGREEMENT § 12.6(a) (2014) ("All disputes arising out of or in connection with the present Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by three arbitrators.").

140. This price competition enables purchasers to purchase generic versions of a drug at a substantially lower price, and/or purchase the brand drug at a reduced price. Therefore, brand drug manufacturers have a significant financial interest in delaying the onset of generic competition, and patients experience substantial cost inflation from that delay.

141. Gilead's ongoing anticompetitive scheme as alleged above will allow it to unlawfully maintain a monopoly and exclude competition in the market for TAF. But for Gilead's ongoing anticompetitive scheme to delay generic TAF competition in the United States, competing drug manufacturers would introduce competing TAF-containing products in the United States.

142. Gilead's ongoing anticompetitive scheme also allows it to utilize its monopoly power over TAF to unlawfully and substantially affect interstate commerce in the markets in the following drugs utilized by physicians as part of HAART treatment regimens: elvitegravir, cobicistat, emtricitabine, and rilpivirine. Gilead implemented its unlawful scheme by (1) unlawfully tying the sale of TAF to the sale of elvitegravir, cobicistat, emtricitabine, and rilpivirine, and (2) conspiring with Japan Tobacco to tie sales of TAF with elvitegravir, cobicistat, and emtricitabine, and conspiring with Janssen to tie sales of TAF with rilpivirine in an effort to obtain and share monopoly profits on the sale of TAF. These acts, in combination and individually, were anticompetitive.

143. But for the anticompetitive, illegal, and ongoing conduct alleged in this complaint, Plaintiff would begin paying less for TAF due to the entrants of competitors in the market for TAF and TAF-containing products.

144. Gilead, by its anticompetitive conduct, threatens to injure Plaintiff by causing it to pay hundreds of millions of dollars in overcharges on its purchases of Genvoya, Odefsey, and Descovy.

145. Defendants' unlawful conduct deprived AHF the benefits of competition that the antitrust laws were designed to protect.

COUNT I
DECLARATORY JUDGMENT OF INVALIDITY
(THE '791, '788, '065, '374, AND '219 PATENTS)

146. The above paragraphs are incorporated herein as set forth above.

147. Upon information and belief, Gilead is the current assignee of the '791, '788, '065, '374, and '219 Patents (collectively, the "TAF Patents").

148. As set forth above, an actual and justiciable controversy exists between AHF and Defendants as to whether the TAF Patents are valid.

149. The TAF Patents are invalid at least because they fail to comply with the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. § 101.

150. The TAF Patents are invalid at least because they are directed to abstract ideas and lack an inventive concept sufficient to transform the claims into a patent-eligible invention under 35 U.S.C. § 101. More specifically, '791, '788, and '065 patents are directed to the abstract idea of using a prodrug of a known compound. And, there is nothing in the claims which would act as an inventive concept sufficient to transform them into patent eligible subject matter.

151. The TAF patents are also invalid in view of extensive prior art that would render them obvious to one skilled in the art. For example, '219 patent claims methods of treating HIV by administering to a patient a triple-drug combination that contain elvitegravir, emtricitabine and tenofovir fumerates. However, those drugs and their use for treating HIV was known and combination therapy to treat HIV was routine. Thus, the claims amount to nothing more than instructions to apply the abstract idea of combination therapy to known HIV drugs. As such, the claims are invalid for being ineligible subject matter.

152. The '374 patent is also invalid as prior art exists that anticipates or renders obvious each of their claims. The '374 patent claims cobicistat, and pharmaceutical compositions containing the cobicistat, that is useful in improving the pharmacokinetics of a co-administered drug. Specifically, cobicistat inhibits cytochrome P450 monooxygenase in a patient so that the pharmacokinetic profile of a co-administered therapeutic agent, such as an HIV drug, is improved.

Co-administrating HIV drugs with other active agents that improve the pharmacokinetic profile of the HIV drug was not a new idea when the cobicistat patent application was first filed in 2007. It was known at that time that cytochrome P450 enzymes metabolize drugs and that the blood plasma levels of drugs which are susceptible to cytochrome P450 enzyme degradation can be maintained or enhanced by co-administration of cytochrome P450 inhibitors, thereby improving the pharmacokinetics of the drug. Many drugs were already known to inhibit cytochrome P450 enzymes, but there was a motivation to find more or improved inhibitors for cytochrome P450 monooxygenase because it was desired to have cytochrome P450 monooxygenase inhibitors that do not have appreciable biological activity other than cytochrome P450 inhibition. Such inhibitors were sought because they would be useful for minimizing undesirable side effects. In addition, it was desirable to have P450 monooxygenase inhibitors that lack significant or have a reduced level of protease inhibitor activity because such inhibitors could be useful for enhancing the effectiveness of antiretroviral drugs while minimizing the possibility of eliciting viral resistance, especially against protease inhibitors. Thus, there was a substantial motivation to develop new cytochrome P450 monooxygenase inhibitor compounds for particular use with HIV drugs and this motivation combined with the known P450 monooxygenase inhibitors already available would guide one towards the specific compound patented as cobicistat.

153. AHF is entitled to judgment declaring that TAF Patents are invalid because they are directed to patent-ineligible subject matter under 35 U.S.C. § 101.

COUNT II
GILEAD'S ILLEGAL MONOPOLIZATION
(VIOLATION OF SECTION 2 OF THE SHERMAN ACT, 15 U.S.C. § 2)

154. Plaintiff incorporates by reference the allegations above, as if fully set forth herein.

155. As described above, at all relevant times, Gilead possessed monopoly power in the relevant market – the market for sales of TAF in the United States. But for Gilead's wrongful conduct, as alleged herein, Gilead would lose its monopoly power in the relevant market.

156. Gilead knowingly, willfully, and wrongfully maintained its monopoly power by improperly bundling TAF with elvitegravir, cobicistat, and emtricitabine to ensure that it can

maintain monopoly prices on TAF.

157. Gilead knew that by bundling TAF with elvitegravir, cobicistat, and emtricitabine, rather than researching and seeking approval on standalone TAF, which is similar to its other standalone tenofovir TDF product (Viread), Gilead could maintain its monopoly pricing on TAF until the shorter of: (1) a competitor completing clinical trials and FDA review of an NDA on a standalone TAF product, (2) all 12 Orange Book listed patents for Genvoya expiring, which will not occur until at least the year 2032, or (3) a competitor filing a Paragraph IV certification on all 12 Orange Book listed patents for Genvoya and the ensuing litigation. Any one of these three periods of time is significantly longer than the period of time it would have taken a generic drug manufacturer to file a Paragraph IV challenge and for any resulting Hatch-Waxman Litigation to have occurred on just the TAF Patents, which could have happened had Gilead released a standalone TAF product.

158. Gilead knew that, by combining TAF with elvitegravir, cobicistat, and emtricitabine, it would reap monopoly profits during this significant difference in time. Further, Gilead knew and intended to deter potential market entrants by creating expensive and time-consuming barriers to entry resulting from the bundling of TAF with elvitegravir, cobicistat, and emtricitabine specifically to create and maintain monopoly profits on the sale of TAF.

159. Without creating these expensive and time-consuming barriers to entry, Gilead would have enjoyed monopoly profits on TAF only for the period of time it took a generic drug manufacturer to prepare and file an ANDA, and the resulting Hatch-Waxman Litigation process. That period of time would be far less than any of the periods of time Gilead ensured by solely releasing TAF as a bundled product with elvitegravir, cobicistat, and emtricitabine.

160. Gilead's knowingly and intentionally bundled TAF with elvitegravir, cobicistat, and emtricitabine in an anticompetitive scheme deliberately designed to block and delay entry of competing versions of TAF to maintain its monopoly power.

COUNT III
CONSPIRACY AND AGREEMENT IN RESTRAINT OF TRADE
(IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1)

161. Plaintiff incorporates by reference the allegations above, as if fully set forth herein.

162. On information and belief, Defendant Japan Tobacco and Defendant Gilead entered into an exclusive license agreement for patents relating to elvitegravir.

163. On information and belief, Japan Tobacco has received between $15-90 million, plus royalties on the sale of products, including Genvoya, containing elvitegravir.

164. On information and belief, Defendant Janseen and Defendant Gilead entered into an exclusive license agreement for patents relating to HAART therapies.

165. On information and belief, Janseen has received royalties on the sale of products containing rilpivirine.

166. On information and belief, Defendants Janseen and Japan Tobacco knew or should have known that their exclusive licenses of patents to rilpivirine and elvitegravir, respectively, were to be used in a conspiracy to reap monopoly profits on tenofovir, and in particular, TAF.

167. Despite this knowledge, Japan Tobacco and Janseemn entered into an agreement and conspiracy with Gilead to license patents covering rilpivirine and elvitegravir with the knowledge and intent that Gilead would use those patents to erect barriers to entry that would create and maintain unjustified monopoly profits on the sale of TAF, and that Defendants Janseen and Japan Tobacco would receive substantial payments for their part in this conspiracy to maintain monopoly profits on TAF.

168. Defendants' acts and conduct are a *per se* or a rule of reason violation of Section 1 of the Sherman Act.

169. Defendants' acts and conduct constitute an agreement, conspiracy, or combination between two or more entities or persons to restrain trade. Defendants' illegal conduct resulted in Plaintiff paying higher prices on TAF than it otherwise would have absent Defendants' conduct.

170. For at least the reasons discussed above, the agreement, conspiracy, or combination between Defendants is an unreasonable restraint of trade in the relevant product

market of TAF under either a *per se* or rule of reason analysis.

171. Defendants' acts and conduct are harmful to and substantially burden competition, including but not limited to, increasing the price paid by Plaintiff for TAF.

172. The restraint that Defendants impose is not justified by any legitimate business purpose.

173. Defendants' unlawful conduct constitutes a contract, combination, or conspiracy and an unreasonable restraint of trade, in violation of the Sherman Act, 15 U.S.C. § 1.

COUNT IV
DEFENDANTS' UNLAWFUL TYING
(VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1)

174. Plaintiff incorporates by reference the allegations above, as if fully set forth herein.

175. The conduct of Gilead, Japan Tobacco, and Janseen, in reaching agreement to tie the sale of TAF to the sale of elvitegravir, cobicistat, emtricitabine, and rilpivirine constitutes an illegal tying arrangement in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

176. The conduct of Gilead and Janssen, in reaching agreement to tie the sale of TAF to the sale of emtricitabine and rilpivirine, constitutes an illegal tying arrangement in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

177. TAF, elvitegravir, cobicistat, emtricitabine, and rilpivirine are all separate and distinct products that compete in distinct and separate markets.

178. Gilead possesses substantial market power over the sale of TAF. For those seeking to purchase TAF, there is no other option than to purchase it through a product offered by Gilead.

179. Gilead, Japan Tobacco, and Janssen have agreed to unlawfully tie the sale of TAF to the sale of elvitegravir, cobicistat, and emtricitabine in one product (Genvoya), emtricitabine and rilpivirine in a second product (Odefsey), and emtricitabine in a third product (Descovy).

180. As a result of this tying arrangement, Plaintiff is forced to purchase elvitegravir, cobicistat, emtricitabine, and rilpivirine when it only wants to purchase TAF.

181. This tying arrangement has substantially affected interstate commerce in the market for drugs complementary to antiretroviral medication used in HAART regimens. It has

reduced output in that market as well.

182. There are no legitimate business justifications or efficiencies for Defendants' tying arrangements that counterbalance their demonstrated anticompetitive effects on the market for drugs complementary to antiretroviral medication used in HAART regimens.

183. These tying arrangements constitute a violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, *per se*, under a "quick look" standard, and under the rule of reason.

COUNT V
DEFENDANTS' UNLAWFUL FORECLOSURE OF COMPETITION
(VIOLATION OF CARTWRIGHT ACT)

184. Plaintiff incorporates by reference the allegations above, as if fully set forth herein.

185. Defendants' coordinated efforts to foreclose competition in the market for drugs complementary to antiretroviral medication used in HAART regimens constitute a violation of the Cartwright Act.

186. Defendants have been able to accomplish this violation because of the individual and collective market power that Gilead wields over the sale of TAF.

187. Defendants' forced tying of elvitegravir, cobicistat, emtricitabine, and rilpivirine with the sale of TAF has achieved and will achieve no legitimate efficiency benefits to counterbalance their demonstrated anticompetitive effects, including the foreclosure of competition in the market for drugs complementary to antiretroviral medication used in HAART regimens.

188. As a result of Defendants' violation of the Cartwright Act, Plaintiff has been and will continue to suffer injury.

COUNT VI
DEFENDANTS' UNFAIR COMPETITION
(VIOLATION OF CALIFORNIA UCL SECTION 17200)

189. Plaintiff incorporates by reference the allegations above, as if fully set forth herein.

190. Defendants' practice of tying the sale of elvitegravir, cobicistat, emtricitabine, and rilpivirine to the sale of TAF is an unfair business practice that makes it impossible for patients to obtain TAF in combination of any other drug complementary to antiretroviral medication (*i.e.*,

TAF). Thus, physicians cannot utilize TAF to optimize a particular HAART regimen for their specific patients. Further, Plaintiff is unable to purchase TAF without purchasing unwanted quantities of elvitegravir, cobicistat, emtricitabine, and rilpivirine.

191. Accordingly, Defendants' practice of tying the sale of TAF to the sale of elvitegravir, cobicistat, emtricitabine, and rilpivirine, has caused patients harm and has caused competitive foreclosure in the market for drugs complementary to antiretroviral medication used in HAART regimens.

192. This practice is an unlawful business act or practice within the meaning of Section 17200 of California's Unfair Competition Law ("UCL").

193. Moreover, Gilead's practice of releasing TAF-containing products only tied to other compounds with corresponding patents that are far stronger than those relating to TAF in an effort to prolong its TAF monopoly is also an unfair business act or practice within the meaning of Section 17200 of California's UCL.

194. Such unfair competitive practices are ongoing and continue to date.

195. Defendants' unfair business practices have caused substantial economic injury to Plaintiff.

196. Such unlawful or unfair business practices are continuing and will continue unless relief enjoining these practices is granted under Section 17204 of the UCL.

COUNT VII
DEFENDANTS' UNFAIR TRADE PRACTICES
(VIOLATION OF NEVADA UNFAIR TRADE PRACTICES LAW)

197. Plaintiff incorporates by reference the allegations above, as if fully set forth herein.

198. Defendants' practice of tying the sale of elvitegravir, cobicistat, emtricitabine, and rilpivirine to the sale of TAF restrained, suppressed, and eliminated competition in the market for drugs complementary to antiretroviral medication used in HAART regimens throughout Nevada.

199. The prices for drugs complementary to antiretroviral medication used in HAART regimens paid in Nevada by AHF were artificially raised and maintained because of Defendants' practice of tying the sale of elvitegravir, cobicistat, emtricitabine, and rilpivirine to the sale of

TAF. AHF was deprived the benefit of free and open competition in the market for drugs complementary to antiretroviral medication used in HAART regimens.

200. Defendants' illegal business practices substantially affected Nevada commerce.

201. As a direct and proximate result of Defendants' illegal conduct, AHF has been injured in its business and property and is threatened with continuing and further injury.

202. Defendants' practice of tying the sale of elvitegravir, cobicistat, emtricitabine, and rilpivirine to the sale of TAF is a violation of Nevada Rev. Stat. Ann. §§ 598A *et seq.* Accordingly, Plaintiff seeks all relief available under Nevada Rev. Stat. Ann. §§ 598A *et seq.*

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully asks the Court to:

a) Declare that each claim of each patent in suit is invalid;

b) Enter judgment declaring the acts and conduct of Defendants as an unlawful violation of the Sherman Act, California Cartwright Act; California Business & Professions Code § 17200; And Nevada Unfair Trade Practices Law;

c) Enter judgment requiring Defendants to pay AHF the monetary damages resulting from the unlawful violations and that those damages be trebled as provided by law;

d) Enter judgment requiring Defendants to pay automatically the attorneys' fees and costs incurred by AHF in bringing these claims as provided by law;

e) Award AHF such other and further relief as this Court may deem just and proper.

f) Issue a declaration under 28 U.S.C. § 2201 that the TAF Patents are invalid;

g) Issue an injunction enjoining Defendants and their agents, representatives, attorneys, employees, and those persons in active

concert or participation with them who receive actual notice here from threatening or initiating infringement litigation against AHF or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of AHF, or charging them either orally in writing with infringement of the Patents-in-Suit;

h) Grant such other and further relief as the Court deems just.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury of all issues triable.

Dated: April 11, 2016

Respectfully submitted,

/s/ Dorian S. Berger

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